FDA 510(k) Premarket Notification

K041242 CANDELA SMOOTHBEAM LASER SYSTEM

CLEARED

Nov 22, 2004
195 days to decision

K041242 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k041242/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 11, 2004
Decision date	Nov 22, 2004
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Candela Corp.**
Location	Natick, MA, US
Contact	LORRAINE CALZETTA PATROVIC
510(k) history	48 submissions · 48 cleared · 1986-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k041242/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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